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JUN 20 2007
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Doc Code: AP.PRE.REQ

PTO/SB/33 (07/05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
792-64 DIV II

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on June 14, 2007

Signature Kathleen J. Goodhand

Typed or printed name Kathleen J. Goodhand

Application Number	Filed
10/721,702	11/25/2003

First Named Inventor	
J. Stinson	
Art Unit	**Examiner**
3738	T. Sweet

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 41,321

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

John S. Sopko
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June 14, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Tradeamrk Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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OIPE IAP22
JUN 20 2007
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 30, 44-59 and 76-84 are pending. Claims 45-49 are withdrawn.

Section 102/103 Rejections

The claims are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,500,013 to Buscemi et al. (hereinafter" Buscemi"). Applicant respectfully transverses.

Buscemi describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added). The fibers 18 may be hollow fibers having an outer diameter not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

Further, a film may be used to cover the fibers 18 to form a cover or may be used to line the inner surface of the main body 11 to form a liner. (Buscemi, column 5, lines 1-18). Thus, the main body 11 of Buscemi is not "basically an inner covering", as set forth in the Advisory action, because Buscemi specifically describes that if an inner covering is desired that it must be added in addition to its main body 11.

Thus, Buscemi fails to disclose, teach or suggest a bioabsorbable endoprosthesis as set forth in amended claim 30, which consists essentially of a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

In other words, Buscemi fails to disclose, teach or suggest that its stent 10 may consist essentially of annularly wound, braided or woven fibers 18. The main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10. Further, the main body 11 of Buscemi is not a mere inner covering because where an inner covering is desired Buscemi adds such a liner to the main body 11 of its stent.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Hertz*, 190 U.S.P.Q. 461, 463 (CCPA 1976) (emphasis in original); MPEP, §2111.3 (8th Ed., Rev. 5 (August 2006)). Further the MPEP states that "for the purposes of searching and applying prior art under U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." (MPEP at §2111.3) (emphasis added).

In the present action, the examiner has taken the more expansive interpretation of the "consisting essentially of" phrase, i.e., "comprising". Applicants, however, respectfully submit that clear indications of the basic and novel characteristics of the present invention are present in the subject application such that the transitional phrase limits the scope of the claims to exclude other structures, in particular the main body 11 of Buscemi.

The specification clearly describes the basic and novel features of the inventive stent having accelerated degradation achieved by filaments having a reservoir, as follows:

> **FIGS. 3a-3f illustrate cross-sections of a known member 10....The degradation rate nearer to the surface 14 of member 10 is relatively slower because pH level at the surface 14 is not substantially changes since acid degradation by-products are more readily flushed or diffused away.** (Specification page 13, paragraph

> beginning with "In comparison...", lines 1-3) (emphasis added)
>
> **[F]ilaments [of the present invention] ... advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions....** (Specification page 14, paragraph beginning with "FIGS. 3a-3f illustrate ...", lines 1-12) (emphasis added)

Moreover, the specification clearly indicates that such filaments, i.e., filaments having hollow reservoirs, are to be used to form the stent to the exclusion of other stent structures, as follows.

> **The tubular and self-expandable body or structure form by the interwoven filaments 20, 30, 40 is a primary prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures.** (Specification page 18, paragraph beginning with "The tubular and ...", lines 1-4) (emphasis added)

Furthermore, the specification also indicates features that do not materially affect the basic and scope characteristics of the claimed invention include those which may be used for aiding implantation of the stent, as follows.

> **However, ... features which enhance or cooperate with the tubular stent and the self-expandable structure or which facilitate the implantation of the structure [may be included, for example] ... radiopaque markers[,] ... a covering or additional interwoven filaments, ... collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these-types nonetheless still substantially consist of the tubular and self-expandable structure formed by the interwoven filaments 20, 30, 40.** (Specification page 18, paragraph beginning with "The tubular and ...", lines 4-13) (emphasis added)

Thus, the specification clearly sets forth the basic and novel characteristics of the present invention. Such basic and novel characteristics exclude the main body 11 of

Buscemi. Further, the reliance on *In re Herz* for an "expansive" reading of "consisting essentially of" is not appropriate in the present matter.

In *In re Herz* the court noted that the specification of subject application described that its composition could include additives, such as dispersants. *In re Hertz*, at 463. The court ruled that the "consisting essentially of" language of the claim would not limit its scope to exclude such additives. Thus, in *In re Herz*, the court ruled that the "consisting essentially of" language in the claims is not a substitute to the teaching of the specification. In the *In re Herz* case, the applicant could not exclude matter from the claims by the "consisting essentially of" language where specification taught that its compositions may specifically include the same matter.

In the present application, the specification clearly teaches that a main body, such as the main body 11 of Buscemi, is not to be included with the limitation of "consisting essentially of". Thus, the subject specification clearly sets forth the basic and novel characteristics of the invention to the exclusion of the required main body 11 of the Buscemi stent 10.

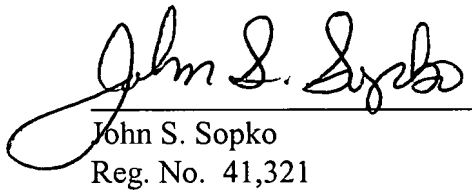
Therefore, the action does not properly apply the correct standard to the "consisting essentially of" phrase in the independent claims when considering the applied art. The "consisting essentially of" limitation in the independent claims is a transitional phrase that limits the scope of the claims. As such, this transitional phrase is used to exclude other stent structures, such as the main body stent structure of Buscemi, from the scope of the claims.

Thus, Buscemi fails to disclose, teach or suggest the bioabsorbable endoprosthesis as set forth in independent claim 30. Reconsideration and withdrawal of the rejection of claim 30, and all claims dependent therefrom, are respectfully requested.

Therefore, Applicants respectfully submit that independent claim 30, and all claims dependent therefrom, are patentably distinct. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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